

1. <u>Waiver of Indictment</u>. Defendant, having been advised of the right to be charged by Indictment, agrees to waive that right and enter a plea of guilty to the charge brought by the United States Attorney in an Information.

Federal Rule of Criminal Procedure 11(c)(1)(B):

2. The Charge. Defendant, having been advised of the right to have this matter tried before a jury, agrees to waive that right and enter a plea of guilty to the following charge contained in the Information: Causing the Introduction of Misbranded Drugs, as charged in Count One, in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).

19

20

21

22

23

24

25

26

27

By entering this plea of guilty, Defendant hereby waives all objections to the form of the charging document. Defendant further understands that before entering Defendant's plea of guilty, Defendant will be placed under oath. Any statement given by Defendant under oath may be used by the United States in a prosecution for perjury or false statement.

- 2. <u>Elements of the Offense</u>. The elements of the offense of Causing the Introduction of Misbranded Drugs, as charged in Count 1 of the Information, are as follows:
 - a. First, the Defendant knowingly caused the introduction into interstate commerce of certain drugs;
 - b. Second, the drugs were misbranded; and
 - c. Third, the Defendant caused the introduction with the intent to deceive.
- 3. <u>Penalties</u>. Defendant understands that the statutory penalties for the offense Causing the Introduction of Misbranded Drugs, as charged in Count 1, are as follows:

Imprisonment for up to three (3) years, a fine of up to ten thousand dollars (\$10,000.00), a period of supervision following release from prison of up to one (1) year, and a one hundred dollar (\$100.00) penalty assessment.

Defendant agrees that the penalty assessment shall be paid at or before the time of sentencing. Defendant agrees that any monetary penalty the Court imposes, including the penalty assessment, fine, costs or restitution, is due and payable immediately, and further agrees to submit a completed Financial Statement of Debtor form as requested by the United States Attorney's Office.

Defendant understands that supervised release is a period of time following imprisonment during which he will be subject to certain restrictions and requirements.

Defendant further understands that if supervised release is imposed and he violates one or more of its conditions, he could be returned to prison for all or part of the term of

1	supervised release that was originally imposed. This could result in Defendant serving a		
2	total term of imprisonment greater than the statutory maximum stated above.		
3	4. Rights Waived by Pleading Guilty. Defendant understands that by pleading		
4	guilty, Defendant knowingly and voluntarily waives the following rights:		
5	a. The right to plead not guilty and to persist in a plea of not guilty;		
6	b. The right to a speedy and public trial before a jury of Defendant's		
7	peers;		
8	c. The right to the effective assistance of counsel at trial, including, if		
9	Defendant could not afford an attorney, the right to have the Court appoint one for		
10	Defendant;		
11	d. The right to be presumed innocent until guilt has been established		
12	beyond a reasonable doubt at trial;		
13	e. The right to confront and cross-examine witnesses against Defendant		
14	at trial;		
15	f. The right to compel or subpoena witnesses to appear on Defendant's		
16	behalf at trial;		
17	g. The right to testify or to remain silent at trial, at which trial such		
18	silence could not be used against Defendant; and		
19	h. The right to appeal a finding of guilt or any pretrial rulings.		
20	5. <u>United States Sentencing Guidelines</u> . Defendant understands and		
21	acknowledges that, at sentencing, the Court must consider the sentencing range calculated		
22	under the United States Sentencing Guidelines, together with the other factors set forth in		
23	Title 18, United States Code, Section 3553(a), including: (1) the nature and circumstances		
24	of the offenses; (2) the history and characteristics of the Defendant; (3) the need for the		
25	sentence to reflect the seriousness of the offense, to promote respect for the law, and to		
26	provide just punishment for the offense; (4) the need for the sentence to afford adequate		

deterrence to criminal conduct; (5) the need for the sentence to protect the public from

28 further crimes of the Defendant; (6) the need to provide the Defendant with educational

and vocational training, medical care, or o	ther correctional treatment in the most effective
manner; (7) the kinds of sentences availab	le; (8) the need to provide restitution to victims
and (9) the need to avoid unwarranted sentence disparity among Defendants involved in	
similar conduct who have similar records.	Accordingly, Defendant understands and
acknowledges that:	

- a. The Court will determine Defendant's applicable Sentencing Guidelines range at the time of sentencing;
- b. After consideration of the Sentencing Guidelines and the factors in 18 U.S.C. 3553(a), the Court may impose any sentence authorized by law, up to the maximum term authorized by law;
- c. The Court is not bound by any recommendation regarding the sentence to be imposed, or by any calculation or estimation of the Sentencing Guidelines range offered by the parties or the United States Probation Department, or by any stipulations or agreements between the parties in this Plea Agreement; and
- d. Defendant may not withdraw a guilty plea solely because of the sentence imposed by the Court.
- 6. <u>Ultimate Sentence</u>. Defendant acknowledges that no one has promised or guaranteed what sentence the Court will impose.
- 7. <u>Statement of Facts</u>. The parties agree on the following facts in support of Defendant's plea of guilty and sentencing. Defendant admits he is guilty of the charged offense.
- a. The Defendant, Dr. Richard MARSCHALL is a licensed naturopathic physician who runs a practice in Port Angeles, Washington.
- b. In February 2009, the Food and Drug Administration (FDA) began investigating the Defendant after it seized a parcel addressed to his practice in Washington. The package contained multiple boxes of Human Chorionic Gonadotropin (HCG) a drug approved for use in treating infertility that was manufactured in China and distributed by a company in India. The FDA gave the Defendant notice that it had

relevant statutes. The Defendant replied by sending an email stating that he was an "endocrinologist" and used HCG to treat infertile patients. However, the Defendant was not a licensed endocrinologist. The package was not released. The Defendant acknowledges that the HCG was misbranded.

- c. In June 2009, the FDA seized a second package of HCG from India intended for Marschall. The FDA gave Marschall notice that the drugs were unapproved new drugs, again citing the relevant FDA laws. Marschall responded that he needed the drugs to treat "certain patients." The package was not released. The Defendant acknowledges that the HCG was misbranded.
- d. In July 2009, the FDA conducted a trash search of the Defendant's clinic and discovered HCG identical to that seized in February 2009. In January 2010, the FDA conducted another trash search and found HCG that had been mailed to him from Florida.
- e. In March 2010, the FDA executed a federal search warrant at the Defendant's business and seized numerous patient records. During the search, the Defendant agreed to be interviewed. He acknowledged that he was prescribing HCG for weight loss purposes and was purchasing the drug from a Canadian website. He further admitted that he knew the drugs came from India. He then admitted that he had lied in his February 2009 email to the FDA in which he claimed that he needed HCG to treat infertile patients. He further acknowledged that he had never treated any patients for infertility with HCG.
- f. The FDA subsequently interviewed multiple former patients of the Defendant that had been prescribed HCG. Each of the patients had been prescribed the drug as part of a weight loss regimen, rather than to treat infertility. Many of the patients never met the Defendant in person, but only had telephone consultations with him.
- g. In August 2010, the Defendant was again interviewed by the FDA.

 First, he acknowledged that he was still treating many patients over the telephone. Then

1 || the stated that when he was purchasing HCG from a Canadian website, he "did order illegally for that short period of time." The Defendant further admitted to lying to the Inspector in 2009 to try convince her to release the package, stating that "I was distracting her. I was diverting her."

- h. The Defendant acknowledges that all of the HCG sei were ordered by the Defendant from a Canadian website, and that he thereby caused the introduction of the drug into interstate commerce. The Defendant further acknowledges that the drugs were misbranded, in that they lacked adequate directions for use and were not exempt from that requirement. The Defendant acknowledges that he caused the introduction of these misbranded drugs with the intent to deceive.
- Sentencing Factors The parties agree and stipulate that the following Sentencing Guidelines provisions apply to this case: A base offense level of 6, pursuant to USSG § 2N2.1.

The parties agree they are free to argue the application of any other provisions of the United States Sentencing Guidelines. Defendant understands, however, that at the time of sentencing, the Court is free to reject these stipulated adjustments, and is further free to apply additional downward or upward adjustments in determining Defendant's Sentencing Guidelines range.

9. Non-Prosecution of Additional Offenses. As part of this Plea Agreement, the United States Attorney's Office for the Western District of Washington agrees not to prosecute Defendant for any additional offenses known to it as of the time of this Agreement that are based upon evidence in its possession at this time, or that arise out of the conduct giving rise to this investigation. In this regard, Defendant recognizes the United States has agreed not to prosecute all of the criminal charges the evidence establishes were committed by Defendant solely because of the promises made by Defendant in this Agreement. Defendant agrees, however, that for purposes of preparing the Presentence Report, the United States Attorney's Office will provide the United States Probation Office with evidence of all conduct committed by Defendant.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

10. <u>Sentencing Recommendation</u>. The United States agrees that it will advocate for a sentence of probation. The government is free to make any argument it deems appropriate regarding other portions of defendant's sentence, including the conditions of release, fines, and restitution.

Defendant is free to recommend any sentence. Defendant understands that neither the Court nor the probation office are bound to follow the parties' recommendations regarding sentencing, and that the Court is free to impose any sentence up to and including the statutory maximum.

- 11. Acceptance of Responsibility. The United States acknowledges that if Defendant qualifies for an acceptance of responsibility adjustment pursuant to U.S.S.G. Section 3E1.1(a), his total offense level should be decreased by two (2) levels because Defendant has clearly demonstrated acceptance of responsibility for Defendant's offense.
- breachs this Plea Agreement, the United States may withdraw from this Plea Agreement and Defendant may be prosecuted for all offenses for which the United States has evidence. Defendant agrees not to oppose any steps taken by the United States to nullify this Plea Agreement, including the filing of a motion to withdraw from the Plea Agreement. Defendant also agrees that if Defendant is in breach of this Plea Agreement, Defendant has waived any objection to the reinstitution of any charges in the Indictment that were previously dismissed or any additional charges that had not been prosecuted.

Defendant further understands that if, after the date of this Agreement, Defendant should engage in illegal conduct, or conduct that is in violation of Defendant's conditions of release or confinement (examples of which include, but are not limited to: obstruction of justice, failure to appear for a court proceeding, criminal conduct while pending sentencing, and false statements to law enforcement agents, the Pretrial Services Officer, Probation Officer or Court), the United States is free under this Agreement to file additional charges against Defendant or to seek a sentence that takes such conduct into consideration. Such a sentence could include a sentencing enhancement under the United

- 13. <u>Waiver of Appeal</u> As part of this Plea Agreement and on the condition that the Court imposes a custodial sentence that is within or below the Sentencing Guidelines range that is determined by the Court at the time of sentencing, Defendant waives to the full extent of the law:
 - a. any right conferred by Title 18, United States Code, Section 3742 to appeal the sentence, including any restitution order imposed; and
 - b. any right to bring a collateral attack against the conviction and sentence, including any restitution order imposed, except as it may relate to the effectiveness of legal representation.

Furthermore, this waiver does not preclude Defendant from bringing an appropriate motion pursuant to to 28 U.S.C. 2241, to address the conditions of Defendant's confinement or decisions of the Bureau of Prisons regarding the execution of Defendant's sentence.

If Defendant breaches this Plea Agreement at any time by appealing or collaterally attacking (except as to effectiveness of legal representation) the conviction or sentence in any way, the United States may prosecute Defendant for any counts, including those with mandatory minimum sentences, that were dismissed or not charged pursuant to this Plea Agreement.

- 14. <u>Voluntariness of Plea</u>. Defendant agrees that Defendant has entered into this Plea Agreement freely and voluntarily, and that no threats or promises, other than the promises contained in this Plea Agreement, were made to induce Defendant to enter this plea of guilty.
- 15. <u>Statute of Limitations</u>. In the event this Agreement is not accepted by the Court for any reason, or Defendant has breached any of the terms of this Plea Agreement, the statute of limitations shall be deemed to have been tolled from the date of the Plea Agreement to: (1) 30 days following the date of non-acceptance of the Plea Agreement by

2

3

4

5

7

8

9

10

11

12

13

14

15

16

17

19

20

21

22

23

24

25

26

•			
1	the Court; or (2) 30 days following the date on which a breach of the Plea Agreement by		
2	Defendant is discovered by the United States Attorney's Office.		
3	16. Completeness of Agreement. The United States and Defendant		
4	acknowledge that these terms constitute the entire Plea Agreement between the parties.		
5	This Agreement binds only the United States Attorney's Office for the Western District of		
6	Washington. It does not bind any other United States Attorney's Office or any other office		
7	or agency of the United States, or any state or local prosecutor.		
8			
9	Dated this day of May, 2011.		
10	Enchard Tharschall		
11	RICHARD MARSCHALL		
12	Defendant		
13	V_{-}		
14	KENNETH KAGAN		
15	Attorney for Defendant		
16	Top (1000)		
17	TODD GREENBERG		
18	Assistant United States Attorney		
19	DIL C		
20	NICHOLAS W. BROWN		
21	Assistant United States Attorney		
22			
23	-		
24			
25			

26

27